REMARKS

The Office Action dated September 4, 2009 has been received and carefully noted. The above amendments and the following remarks are being submitted as a full and complete response thereto.

Claims 1-2, 4-6, 8-11, 13, 15, 17, 29-31, and 48-61 are pending in this application, with claims 1, 29, 48, and 59 being independent. By this Amendment, claims 1, 11, 13, 15, 17, 29, 48, 56-57, and 59 have been amended. Support for these amendments may be found at least in paragraph [0059] of the published version of the specification. No new matter has been added.

Applicants respectfully request reconsideration and withdrawal of all outstanding rejections.

Response to Examiner's Notation

The Office Action contained a note that previously-presented new claims 48 and 59 included strikethrough. Applicants submit that claims 48 and 59 have been presented above without the strikethrough text, as required.

Rejection under 35 U.S.C. §112, First Paragraph

Claims 1, 2, 4-6, 8-11, 13, 15-17, and 29-31 were rejected under 35 U.S.C. §112, first paragraph. The Office Action continues to take the position that the claims lack enablement for the reasons of record. Applicants respectfully traverse this rejection and reconsideration is requested.

Applicants submit that the Office Action has characterized the rejection as based on alleged lack of enablement for "differentiation of any/all forms of TSE by mere alteration of

level of nonspecified proteins." However, Applicants submit that the previously-presented amendments to these claims clarify that the comparison is being made in order to determine whether or not a subject is suffering from ***BSE, vCJD, or CJD***, and that the determination is made with respect to a reference amount of a polypeptide having a particular molecular weight. As such, Applicants submit that the claims do not encompass "any/all forms of TSE" or "nonspecified proteins."

In view of the remarks set forth above, and the guidance provided in the specification and examples, Applicants submit that undue experimentation would not be required for one skilled in the art to carry out the presently-claimed invention, and respectfully request withdrawal of the rejection of claims 1, 2, 4-6, 8-11, 13, 15-17, and 29-31 under 35 U.S.C. §112, first paragraph.

Claims 48-61 were also rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking enablement on the grounds that the specification, while enabling the specific increase/presence/absence/decrease of specified proteins for specific TSE diseases, allegedly does not provide enablement for the scope of these claims. Applicants respectfully traverse this rejection and reconsideration is requested.

Applicants submit that the Office Action has characterized the rejection as based on alleged lack of enablement for "diagnosis of any/all TSE comprising subjecting a sample of CSF, blood, plasma, or serum to mass spectrometry, thereby determining the amount of a polypeptide in the sample, comparing the amount to that observed in normal CSF, blood, plasma, or serum, wherein an increase or decrease in the polypeptide in the subject's body fluid compare to the reference indicates any/all TSE in the subject." However, Applicants submit that claims 48-61 recite that the comparison is being made in order to determine whether or not a subject is suffering from ***BSE, vCJD, or CJD***, and that the determination is made with respect to a

reference amount of a polypeptide having a particular molecular weight. As such, Applicants submit that claims 48-61 do not encompass "any/all forms of TSE" or "nonspecified proteins."

In view of the remarks set forth above, and the guidance provided in the specification and examples, Applicants submit that undue experimentation would not be required for one skilled in the art to carry out the presently-claimed invention, and respectfully request withdrawal of the rejection of claims 48-61 under 35 U.S.C. §112, first paragraph.

Rejection under 35 U.S.C. §112, Second Paragraph

Claims 1, 2, 4-6, 8-11, 13, 15-17, 29-31, and 48-61 were rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Applicants respectfully traverse this rejection and reconsideration is requested.

The Office Action has taken the position that the presently-claimed invention relates to detection of polypeptides "only designated as having a molecular weight of about one from a list." The Office Action indicates that it is unclear how to distinguish BSE, vCJD, or CJD from another disease state that presents polypeptides of the same molecular weight. In particular, the Office Action cites U.S. Patent No. 6,416,962 relating to detection of *M. tuberculosis* infection, and inquires as to how a determination of BSE, vCJD, or CJD based on detection of such a peptide could be made distinguished from, e.g., an *M. tuberculosis* infection (or any other disease state that presents peptides of the same molecular weights that are claimed).

Initially, Applicants disagree with the characterization in the Office Action that the mass ranges set forth in U.S. Patent No. 6,416,962 are "about" those of the presently-claimed invention. In the '962 patent, the mass ranges are given to the nearest 1000 Da, i.e., 10 kDa

(10,000 Da), 14 kDA, 16 kDa, 10-16 kDa, etc. Since the lowest mass given in the '962 patent is 10 kDa, it is unlikely that one skilled in the art of mass spectrometry would consider the majority of the claimed molecular weights to be "about" 10 kDa, because 27 of the 29 polypeptides claimed are more than 10% different in mass. This example is merely hypothetical, as the proteins detected in the '962 patent are also easily distinguished because they are bound protein-antibody complexes. It is the protein-antibody complexes that are detected in the samples of the '962 patent, and antibodies are known to those skilled in the art to have a mass of about 180,000 Da/180 kDa, for a combined mass of peptide and antibody of about 190,000 Da/190 kDa. In contrast, the methods of the presently-claimed invention recite that peptides having the given molecular weights are detected using ***mass spectrometry***, and do not rely upon antibody-protein binding for detection.

In addition, Applicants submit that the claims specifically state that they relate to a "method of diagnosis of a transmissible spongiform-encephalopathy (TSE) selected from the group consisting of Bovine Spongiform Encephalopathy (BSE), variant Creutzfeldt-Jakob Disease (vCJD), and Creutzfeldt-Jakob Disease (CJD) ***in a subject suspected of suffering from BSE, vCJD, or CJD***." One skilled in the art would not be confused by the fact that a particular detected peptide might theoretically be present in, for example, an *M. tuberculosis* infection, because a subject suspected of suffering from BSE, vCJD, or CJD would present with different symptoms than a subject suspected of suffering from an *M. tuberculosis* infection. As noted in the published version of the specification at paragraph [0003], TSEs are often accompanied by symptoms such as ataxia, dementia, and psychiatric disturbances. Even if the subject does not present with symptoms of BSE, vCJD, or CJD, one skilled in the art would be able to determine

whether the subject was at risk of developing BSE, vCJD, or CJD by considering other factors, such as the subject's species (i.e., BSE affects ruminant animals such as cattle).

Finally, Applicants submit that using the term "about" to describe the claimed molecular weights does not render the claims indefinite. The specification clearly indicates in paragraph [0059] that "the term 'about' in connection with the molecular weights means a variation of about 1%, preferably 0.5%, and more preferably within about 0.1% above or below the quoted value." Without conceding the propriety of this rejection, Applicants have amended the independent claims to recite that the molecular weights are within 1% of the recited values.

In view of the remarks presented above, Applicants submit that the presently-claimed invention is not indefinite, and respectfully request withdrawal of the rejection of claims 1, 2, 4-6, 8-11, 13, 15-17, 29-31, and 48-61 under 35 U.S.C. §112, second paragraph.

CONCLUSION

Applicants respectfully submit that this application is in condition for allowance and such action is earnestly solicited. If the Examiner believes that anything further is desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact Applicants' undersigned counsel at the telephone number listed below to schedule a personal or telephone interview to discuss any remaining issues.

The undersigned counsel would accordingly appreciate the Examiner telephoning counsel prior to the expiration of the six-month statutory period (i.e., March 4, 2010) to indicate the disposition of this Amendment. Additionally, should the Examiner believe that anything further is necessary in order to place this application in better condition for allowance, the Examiner is also requested to contact the undersigned at the telephone number listed below.

In the event that this paper is not being timely filed, the Applicants respectfully petition for an appropriate extension of time. Any fees for such an extension, together with any additional fees that may be due with respect to this paper, may be charged to Counsel's Deposit Account Number 01-2300, referencing Docket Number 108140-00030.

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Respectfully submitted,

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